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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,467	04/09/2001	Hiroshi Shinoki	JG-SIK-5063/500676.20003	8683

7590 08/21/2003  
REED SMITH LLP  
375 Park Avenue  
New York, NY 10152

EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/21/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/829,467

Applicant(s)

SHINOKI ET AL.

Examiner

Jeffrey Siew

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6-8,10,12,14,16,18,20-26 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,11,13,15,17,19,27 & 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *seq error report*.

### **DETAILED ACTION**

1. The response and amendment filed 5/27/03 has been entered. Pending claims to be examined are claims 1,3,5,7,9,11,13,15,17,19,27 & 31.

### ***Election/Restrictions***

2. This application contains claims 2,4,6-8,10,12,14,16,18,20-26,28-30 are drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

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2. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

3. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

**Applicant Must Provide:**

X An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

X A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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**THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE  
AMENDMENT**

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A) Claim 5 is indefinite because it is unclear as to what each variable range encompasses. It appears that part of the claim has been deleted from original claim 5.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1,3,5,7,9,11,13,15,17 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brush et al (US5,986,086 Nov. 16, 1999) in view of Haugland et al (US5,719,031 Feb 17, 1998)

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Brush teach a fluorescent nucleotide represented by formula A-B-C (abstract) where A represents a residue of natural or synthetic nucleotide (see col. 3 lines 50-60) and binds to B at base moiety where B is a divalent linking group or single bond (see col. 3 lines 35-50) and C represents a monovalent group derived from fluorescent dye have 0 sulfonic acid group or phosphoric acid group (see all figures and also col.2 lines 5, col.2 line 33 nonsulfonated cyanine dye). They teach that X and Y are each independently selected from group consisting O,S (see abstract). They teach that m is an integer 1,2 or 3 (see abstract Brush term is r for the claimed m). They teach  $R^1$  and  $R^2$  each independently represent a hydrogen atom or alkyl group capable of covalently binding to B (see abstract). They teach  $R^4$  is hydrogen H and equivalent  $R^3$   $R^9$   $R^8$  are hydrogen or  $R^5$  is hydrogen (see abstract and figure). Brush also teaches of sulfonated cyanines (see col. 1 lines 53). They also teach that B may be sulfide or amine bond (see col.3 line 39). They also teach  $R^1$  with carboxyl groups (see col.3 lines 15-19).

Brush et al do not teach having a water soluble group other than a sulfonic acid group, phosphoric acid or carboxylic group.

Haugland et al teach using sulfanamide in the dye to attach to nucleotide (see whole doc esp. col. 7 line 35).

One of ordinary skill in the art would have been motivated to apply Haugland et al's teaching of sulfanamide into Brush fluorescent dye in order to attach the dye to the nucleotide. Haugland states that sulfanamide or amine successfully bound the oligonucleotide to the fluorophore. It would have been prima facie obvious to apply Haugland et al's successful use of sulfanamide to attach dyes to oligonucleotides in order to successfully attach fluorescent dyes to Brush et al's nucleotide.

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6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brush et al (US5,986,086 Nov. 16, 1999) in view of Haugland et al (US5,719,031 Feb 17, 1998) in further view of Mao et al (Oct 10, 2000 102(e) date 9/23/1997).

The teachings and suggestions of Brush et al and Haugland et al are described previously.

Brush et al do not teach aminoallyl linkage.

Mao et al teach aminoallyl linkage in binding dye to nucleotides (see col.16 line 64).

One of ordinary skill in the art would have been motivated to apply Mao et al's aminoallyl linkage to Brush et al's dye in order to provide stable bond. As Mao et al teach the successful use of aminoallyl bonds to attach dyes, it would have been prima facie to apply the aminoallyl linkage to Brush et al's dye in order to create a strong link to the nucleotide.

## SUMMARY

7. No claims allowed.




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*Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

  
JEFFREY SIEV  
PRIMARY EXAMINER  
3/19/03